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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,455	04/05/2006	Moise Azria	PA/4-33288A	9884

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
XIE, XIAOZHEN	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
10/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,455	AZRIA ET AL.	
	Examiner	Art Unit	
	XIAOZHEN XIE	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,17-19 and 21-23* is/are pending in the application.

4a) Of the above claim(s) *17-19 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,21 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060120*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The Information Disclosure Statements (IDS) filed 20 January 2006 has been entered. Applicant's amendment of the specification filed on 20 January 2006 has been entered. Applicant's preliminary amendment of the claims filed on 20 January 2006 has been entered.

Election/Restrictions

Applicant's election of Group I, claims 1-10, 21 and 23, in the reply filed on 18 July 2008, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11-16 and 20 have been cancelled. Claims 1-10, 17-19 and 21-23 are pending. Claims 17-19 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-10, 21 and 23 are under examination.

Information Disclosure Statement

The information disclosure statement filed 20 January 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Applicant fails to provide a

copy for each of the listed foreign patent document and non-patent literature. It has been placed in the application file, but the information referred to therein has not been considered.

Further, reference "BC" (i.e., Japanese Patent No. 05 345729) should be placed in category "Foreign Patent Documents".

Specification

The instant specification does not include lettered section heading (see the following), as suggested in 37 CFR 1.77(b).

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

Claims 8, 9 and 21 are objected to because of the following informalities:

Claims 8 and 9 use acronyms, for example, "5-CNAC", "SNAD", and "SNAC". While the claims can reference acronyms, the material presented by the acronym must be clearly set forth at the first use of the acronym.

Claim 21 has a typographical error: "said patent" should be "said patient".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim1-10, 21 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method of treating osteoarthritis or inhibiting resorption and/or normalizing turnover of subchondral bone in a patient having osteoarthritis or osteoporosis, or in a postmenopausal woman, comprising administering to said patient a therapeutically effective amount of a naturally occurring salmon calcitonin, or a conjugated form thereof with a polymer,

does not reasonably provide enablement for preventing osteoarthritis, or administering the drug to any patient, nor using any calcitonin, including calcitonin of any species, and variants, analogues and derivatives of calcitonin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See also *Ex parte* Forman, 230 USPQ 546 (BPAI 1986).

The claims recite “preventing osteoarthritis in a patient in need thereof”, and “inhibiting resorption and/or normalizing turnover of subchondral bone in a patient in need thereof”. The specification, however, does not define which patient population is “in need thereof”. Thus, the claims read on administering the calcitonin to any patient, including patients with any disease, and including those healthy individuals without

osteoarthritis, osteoporosis, or post-menopause, i.e., prophylactic treatment. The specification discloses a method for treating osteoarthritis by administering to a patient with the disease a composition comprising salmon calcitonin, which is formulated with a delivering agent (such as 5-CNAC, SNAD and SNAC, or disodium salt thereof) into a particle form of oral pharmaceutical composition. The specification discloses that the oral salmon calcitonin composition was administered to osteoarthritis patients at a dosage of either 0.5 mg or 1 mg once daily (Example 7), or administered to postmenopausal women at a dosage of 0.15, 0.4, 1.0 or 2.5 mg daily (Example 8). The specification discloses that the treatment suppresses urinary collagen type II degradation products in these patients, indicating reduced cartilage degradation. The specification, however, does not provide support that the calcitonin can be administered to any patient (i.e., patients with any disease) or healthy individuals without osteoarthritis, osteoporosis, or post-menopause, nor that prophylaxis can be achieved without adverse effects in these individuals. Shah et al. (Endocrinology, 1994, Vol. 134(2): 596-602) teach that secretion of a calcitonin-like ectopic peptide(s) has been reported in several human tumors, such as breast, renal, lung, and gastric carcinoma. Shah et al. found that salmon calcitonin stimulates growth of human prostate cancer cells (see Abstract). Further, Chigurupati et al. (Cancer Res., 2005, 65(18):8519-8529) reported that calcitonin stimulates multiple stages of angiogenesis by directly acting on endothelial cells, suggesting its role in promoting tumor growth by regulating intratumoral vascularization (see Abstract). Therefore, the art teaches that it is not desirable to administer calcitonin into patients having cancer cells (e.g., prostate cancer

cells). The specification does not teach what the outcome would be if administered the agent(s) into a patient with other disease or to a normal individual. It requires large quantity of experimentation to determine the patient population and treatment outcomes.

Further, the claims read on the use of any calcitonin, including calcitonin of any species, and including variants, analogues and derivatives of calcitonin. The specification discloses naturally occurring calcitonins from salmon, (Asu 1-7)-eel, and human, or a conjugated form thereof with a polymer. The specification discloses that administration of salmon calcitonin at a dosage range of 0.4 to 2.5 mg into osteoarthritis patients or post-menopausal women led to reduced cartilage degradation and bone resorption. The specification, however, does not provide sufficient guidance and support that any calcitonin can exhibit the therapeutic effects. The prior art (Ghirri et al. US 6,352,974 B1) teaches that the activities of calcitonins from different species vary dramatically, for example, porcine and human calcitonins typically have an activity of 100 to 200 IU/mg, and salmon calcitonins typically have an activity of up to 6500 IU/mg (col. 3, lines 38-40). While the specification describes the dosage ranges preferably for the treatment method, e.g., 0.4-2.5 mg, the specification, however, fails to provides support that a calcitonin having >60-fold less activity can still function to reduce cartilage degradation and inhibit bone resorption. Also, the specification does not sufficient teachings for using variants, analogues and derivatives of calcitonin in the claimed methods. Epand et al. (Eur. J. Biochem., 1990, Vol. 188:633-635) teach that a single amino acid substitution of salmon calcitonin, L12A, leads to a dramatic decrease in

activity (from 4500 IU/mg to 220 IU/mg) (pp. 634, Table 1). Therefore, calcitonins from different species, and variants, analogues and derivatives thereof, may vary substantially in activity, and could function very differently in a clinical setting from the naturally occurring salmon calcitonin that Applicant has disclosed.

Without sufficient guidance from the specification, one of skill in the art would evaluate a large number of non-exemplified calcitonins to determine if these molecules can provide therapeutic effects in treating osteoarthritis and in inhibiting resorption and/or normalizing turnover of subchondral bone in a patient, and to determine if these molecules can provide prophylactic treatment in any patient. The scope of patent protection sought by Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification.

Due to the large quantity of experimentation necessary to determine if any calcitonin can be used for treating, as well as preventing, osteoarthritis in a patient, the lack of direction/guidance presented in the specification, the absence of working examples, the complex nature of the invention, the state of the art which establishes the unpredictability of the effects of protein structure on function (e.g., calcitonins vary dramatically in activity), and teaches the unpredictability of the effects of calcitonin in patient with different diseases (e.g., calcitonin may promote cancer cell growth), and the breadth of the claims which reads on using any calcitonin molecule, and reads on administering to any patient and prophylaxis, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bay et al. (US 20020065255 A1, Pub. Date: 30 May 2002).

The claims are directed to a method of preventing and/or treating osteoarthritis, or inhibiting resorption and/or normalizing turnover of subchondral bone, in a patient in need thereof comprising administering to said patient a therapeutically effective amount of a calcitonin in free or salt form (claims 1, 2); wherein the calcitonin is delivered orally in a composition comprising the calcitonin and a delivery agent (claims 3, 4), wherein the calcitonin is delivered with an effective dosage of an oral pharmaceutical composition comprising calcitonin, at least one pharmaceutically acceptable pH-lowering agent, at least one absorption enhancer, and an enteric coating (claim 6); whereas the calcitonin is a salmon calcitonin (claim 7); whereas said delivery agent is selected from the group of 5-CNAC, SNAD and SNAC, or disodium salt thereof (claims 8, 9); and whereas said pharmaceutical composition comprises a delivery agent in micronized form (claim 10).

Bay et al. teach a composition comprising a delivery agent, which is a disodium salt of 5-CNAC, SNAD, or SNAC, and an active agent, such as calcitonin [0010] [0015]. Bay et al. teach that the disodium salts of the delivering agents, or the hydrates and solvates thereof, have greater efficacy for delivering the active agent than the

corresponding monosodium salts and free acids [0009]. Bay et al. teach administering the composition comprising a pharmacologically or therapeutically effective amount of the active agent into a subject (e.g., a human) in need thereof [0036] [0038]. Because the specification does not define the patient population that are “in need thereof”, and the claim language encompasses “prophylaxis”, Bay et al.’s teaching meets the limitation of "a patient in need thereof". Bay et al. teach that the calcitonin includes salmon, eel, porcine and human calcitonin [0035]. Bay et al. teach that the composition may be formulated into an oral dosage unit form, e.g., particles, powders or sachets (micronized form) [0015] [0042]. Bay et al. also teach that the composition may further comprise additives, such as a surfactant (an absorption enhancer), a plasticizer, a lubricant, a dosing vehicle, a solubilizer, an excipient, and other additives including a pH adjuster, phosphate buffer salts and citric acid (pH-lowering agent) [0039]. Bay et al. teach that the composition typically has a sustained release coating [0036]. Since the specification does not define “an enteric coating”, the sustained release coating taught by Bay et al. meets the limitation of “an enteric coating”.

Therefore, Bay et al. anticipate the instant claims.

Claims 1-7, 10, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghirri et al. (US 6,352,974 B1, Date of Patent: 5 March 2002).

The claims are directed to a method of preventing and/or treating osteoarthritis, or inhibiting resorption and/or normalizing turnover of subchondral bone, in a patient in need thereof comprising administering to said patient a therapeutically effective amount

of a calcitonin in free or salt form (claims 1, 2); wherein the calcitonin is delivered orally in a composition comprising the calcitonin and a delivery agent (claims 3, 4), or in a composition comprising the calcitonin which is conjugated to a polymer molecule (claim 5); wherein the calcitonin is delivered with an effective dosage of an oral pharmaceutical composition comprising calcitonin, at least one pharmaceutically acceptable pH-lowering agent, at least one absorption enhancer, and an enteric coating (claim 6); whereas the calcitonin is a salmon calcitonin (claims 7, 23); whereas said pharmaceutical composition comprises a delivery agent in micronized form (claim 10); and wherein the method comprising administering a pharmaceutical composition comprising between 0.4 and 2.5 mg of a calcitonin (claim 21).

Ghirri et al. teach oral calcitonin pharmaceutical compositions comprising calcitonin and gelatin (delivery agent) (see claims). Ghirri et al. teach that calcitonins are used to treat a variety of conditions, e.g., Paget's disease, post-menopausal osteoporosis (col. 2, lines 31-35). Ghirri et al. teach that the calcitonin may be naturally occurring calcitonin, such as salmon, eel, porcine or human, or a synthetic calcitonin (col. 5, lines 14-24), and that the calcitonin may be conjugated to a polymer, e.g., to a polyalkylene glycol moiety (col. 5, lines 25-29). Ghirri et al. teach that the oral calcitonin pharmaceutical compositions may be milled and/or sieved to provide a particulate solid, e. g., granules or a powder (col. 5, lines 42-47). Ghirri et al. teach that the composition should be enteric coated to prevent gastric degradation (col. 6, lines 5-7). Ghirri et al. also teach other additives that can be included in the compositions, for example, adding phosphoric acid to adjust the pH to 4 (col. 10, Example 2), and adding absorption

enhancers to the compositions (Example 6). Ghirri et al. teach that the compositions preferably have a unit dose of active material from about 20 IU to about 600 IU (col. 6, lines 21-26); for porcine and human calcitonin, each milligram (mg) has 100-200 IU activity, and for salmon calcitonin, each mg has up to (i.e., less than) 6500 IU activity (col. 3, lines 38-40). Therefore, the unit dose of calcitonin in Ghirri et al.'s composition meets the instant limitation of "between 0.4 and 2.5 mg of a calcitonin".

Therefore, Ghirri et al. anticipate the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 2 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9 and 10 of copending Application No. 11/577,127. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claims 1, 9 and 10 of the copending Application No. 11/577,127 are directed to a method of treating a severe form of bone loss diseases or osteoporosis, in a patient in need thereof, comprising administering to the patient an effective amount of calcitonin. The method of the copending Application No. 11/577,127 differs from the instant application in that the instant method is drawn to a method of inhibiting resorption and/or normalizing turnover of subchondral bone in a patient in need thereof comprising administering to the patient an effective amount of calcitonin. The instant claims are broader in scope, encompassing a genus of diseases or patient populations related to the species claimed in the cited copending Application No. 11/577,127. Thus, they differ in scope. The copending claims anticipate the instant, broader claims, and thus an obviousness-type double patenting rejection is appropriate.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 7 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. 12/132,642. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claims 13-15 of copending Application No. 12/132,642 are directed to a method of treatment of bone related diseases comprising administering to a patient in need of such treatment a composition suitable for the oral delivery which comprises a calcitonin, e.g., salmon calcitonin, and a delivery agent which is in micronized form. The method of the copending Application No. 12/132,642 differs from the instant application in that the instant methods are drawn to a method of preventing and/or treating osteoarthritis, and a method of inhibiting resorption and/or normalizing turnover of subchondral bone in a patient in need thereof, comprising administering to the patient an effective amount of calcitonin. The instant claims are broader in scope, encompassing patient populations related to the species claimed in the cited copending Application No. 12/132,642, and further encompassing patient populations that need prophylactic treatment. Thus, the copending claims anticipate the instant claims, and an obviousness-type double patenting rejection is appropriate.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 7, 8, 21 and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 28 and 29 of copending Application No. 12/093,383, in view of Ghirri et al. (US 6,352,974 B1, Date of Patent: 5 March 2002).

Claims 26, 28 and 29 of the copending Application No. 12/093,383 are directed to a method of treating a disease caused by abnormal bone resorption, or treating an arthritic disease in a patient in need thereof, comprising administering to the patient an oral pharmaceutical composition comprising a poly(amino acid) and a delivery agent. The method of the copending Application No. 12/093,383 differs from the instant application in that the instant methods are drawn to a method of preventing and/or treating osteoarthritis, and a method of inhibiting resorption and/or normalizing turnover of subchondral bone in a patient in need thereof, comprising administering to the patient an effective amount of calcitonin. Ghirri et al. teach the use of an oral calcitonin pharmaceutical composition (e.g., salmon calcitonin) for treat a variety of conditions caused by abnormal bone resorption, e.g., Paget's disease, osteoporosis. Ghirri et al. teach the dosages and the delivery agent as recited in the claims (see above 102(b) rejection). Therefore, it would have been obvious to use a calcitonin, e.g., salmon calcitonin, in the method of the copending Application No. 12/093,383. One having ordinary skill in the art would have been motivated to do so, because Ghirri et al. teach that the calcitonin can be used for treating patient having the same diseases as in the

copending Application No. 12/093,383. Such a modification provides a reasonable expectation of successfully treating the diseases.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.
September 24, 2008

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646